**PATENT COOPERATION TREATY**

**PCT**

**INTERNATIONAL SEARCH REPORT**

(PCT Article 18 and Rules 43 and 44)

<table>
<thead>
<tr>
<th>Applicant's or agent's file reference</th>
<th>FOR FURTHER ACTION</th>
<th>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</th>
</tr>
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<td>01235-36031.PCT</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>International application No.</th>
<th>International filing date (day/month/year)</th>
<th>(Earliest) Priority Date (day/month/year)</th>
</tr>
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<tr>
<td>PCT/US 15/47556</td>
<td>28 August 2015 (28.08.2015)</td>
<td>28 August 2014 (28.08.2014)</td>
</tr>
</tbody>
</table>

| Applicant                          | LIPOCINE INC.                                |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets. It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language**, the international search was carried out on the basis of:
      - [X] the international application in the language in which it was filed.
      - [ ] a translation of the international application into _______________ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
   b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6(b)(a)).
   c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. 1.

2. [ ] Certain claims were found unsearchable (see Box No. II).

3. [ ] Unity of invention is **lacking** (see Box No. III).

4. With regard to the **title**,
   - [X] the text is approved as submitted by the applicant.
   - [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,
   - [ ] the text is approved as submitted by the applicant.
   - [X] the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,
   a. the figure of the drawings to be published with the abstract is Figure No. 1 ____________
      - [X] as suggested by the applicant.
      - [ ] as selected by this Authority, because the applicant failed to suggest a figure.
      - [ ] as selected by this Authority, because this figure better characterizes the invention.
   b. [ ] none of the figures is to be published with the abstract.
A compositions and dosages forms that allow for high drug loading for highly lipophilic drugs while maintaining excellent oral bioavailability. The pharmaceutical compositions and unit dosage forms described herein can reduce pill burden for hydrophobic drugs like (8R,9S,10R,13S,14S,17S)-10,13-dimethyl-3-oxo-1,2,6,7,8,9,11,12,14,15,16,17-dodecacyclopent[a]phenanthren-17-yl tridecanoate or (8R,9S,10R,13S,14S,17S)-10,13-dimethyl-3-oxo-1,2,6,7,8,9,11,12,14,15,16,17-dodecacyclopent[a]phenanthren-17-yl tetradecanoate, and can be formulated at advantageous drug loads (e.g., greater than 23%) while providing suitable bioavailability (e.g., capable of treating a hypogonadal male with less than 10 unit dosage forms per day) that allows for reduction in pill burden and accordingly improved patient adherence or compliance. Additionally, the composition (e.g., dosage form) has a release profile that is suitable for providing bioavailable API and the release profile is stable over time (e.g., under storage conditions).
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC(B) - A61K 31/568; A61K 9/48 (2015.01)
CPC - A61K 31/56; A61K 31/568; A61K 9/4858

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(B) - A61K 31/568; A61K 9/48 (2015.01)
CPC - A61K 31/56; A61K 31/568; A61K 9/4858

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Patents and NPL (classification, keyword, search terms below)
USPC - 424/452; 514/171

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
search terms: oral testosterone ester tridecanoate tetradecanoate hypogonadal male capsule hard gel soft gel treat octadecanoic acid
dissolution release profile stability clear liquid isopropyl-5-methylocyclohexanone

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
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<tr>
<td>X</td>
<td>US 2013/0225544 A1 (Nachaeangi et al.) 29 August 2013 (29.08.2013), para [0007], [0015], [0036], [0072], [0085], [0090], [0094], [0095], [0099]-[0100], [0103], [0107], [0109], [0112]-[0114], [0117], [0144]-[0145], [0168], [0185]; Fig 1; Table 1</td>
<td>1-21, 24-26, 28-35</td>
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<tr>
<td>Y</td>
<td>US 2012/0244215 A1 (Gillyar et al.) 27 September 2012 (27.09.2012), para [0008], [0127], [0130]-[0134]; Table XII, XVII</td>
<td>22-23, 27</td>
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<tr>
<td>Y</td>
<td>US 2003/0022875 A1 (Wilson et al.) 30 January 2003 (30.01.2003), para [0014], [0031], [0032], [0062], [0063], [0103]</td>
<td>1-35</td>
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</tbody>
</table>

Further documents are listed in the continuation of Box C.

* Special categories of cited documents:
  "A" document defining the general state of the art which is not considered to be of particular relevance
  "E" earlier application or patent but published on or after the international filing date
  "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
  "O" document referring to an oral disclosure, use, exhibition or other means
  "P" document published prior to the international filing date but later than the priority date claimed
  "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
  "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
  "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
  "&" document member of the same patent family

Date of the actual completion of the international search
23 November 2015 (23.11.2015)

Date of mailing of the international search report
28 DEC 2015

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
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Facsimile No. 571-273-8300

Authorized officer: Lee W. Young
PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)